Potter Anderson Corroon LLP

1313 North Market Street
P.O. Box 951
Wilmington, DE 19801- 0951
302 984 6000
www.potteranderson.com

Bindu A. Palapura
Partner
Attorney at Law
bpalapura@potteranderson.com
302 984-6092 Direct Phone
302 658-1192 Firm Fax

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VIA ELECTRONIC FILING
The Honorable Colm F. Connolly
United States District Judge
J. Caleb Boggs Federal Building
844 N. King Street
Unit 31, Room 4124
Wilmington, DE 19801-3555

Re: *Par Pharm., Inc. v. Eagle Pharms., Inc.*, C. A. No. 18-823-CFC

Dear Judge Connolly:

This firm, together with Kirkland & Ellis LLP, represents Defendant Eagle Pharmaceuticals, Inc. ("Eagle") in the above-captioned action. In accordance with ¶5 of the Scheduling Order (D.I. 20), we write regarding three disputes that have arisen with respect to the Protective Order for this action: (1) whether the identity of Eagle's vasopressin active pharmaceutical ingredient (API) supplier must be disclosed to Par's in-house counsel (¶2(c)(i)); (2) whether Par's identified in-house counsel, Lawrence Brown and Matthew Maletta, should be designated under the Protective Order (¶7(b)(i)); and (3) the scope of the "FDA Bar," *i.e.*, whether designated in-house counsel should be permitted to work on FDA documents regarding their *own* employer's drug approval application(s) (¶2(k)(ii)). The parties made a reasonable effort to resolve the disputes, including oral communications involving Delaware counsel for both parties (*See* Ex. 2). For the following reasons, Eagle respectfully requests that the Court enter its proposed Protective Order (Ex. 1).

I. Disputes 1 and 2: Eagle's API Supplier And Par's Proposed In-House Counsel

The background to the first two disputes lies in parallel antitrust litigation brought by a third party, Fresenius Kabi USA, LLC, against Par in the District of New Jersey. Filed in July 2016, Fresenius' Complaint alleges that "Par has engaged in an extensive anticompetitive scheme to maintain its monopoly power [in the market for vasopressin] and unlawfully interfere with competitors' efforts to enter or re-enter the relevant market," leading Par to increase vasopressin prices "by 2600% – from $5.13 per vial to $138.60 per vial." (Ex. 3 (*Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, C.A. No. 2:16-04544 (SDW)(LDW), Dkt. 1 (D.N.J. July 27, 2016)), ¶¶8,14.) Central to Fresenius' cause of action is its allegation that "Par has leveraged its position as the sole FDA-approved manufacturer of Intravenous Vasopressin Injection ***to prohibit actual or potential competitors, such as Fresenius Kabi, from accessing Vasopressin API, even solely for the purpose of filing an ANDA***." (*Id.*, ¶14.) Specifically, Fresenius alleges that Par entered into unlawful agreements with all then-qualified API suppliers, precluding them from supplying API

to Par's prospective competitors. (*Id.*, ¶¶74-109.) According to Fresenius, "Par's actions to block access to suppliers of Vasopressin API . . . have been taken with the purpose and intent of monopolizing or maintaining a monopoly in the relevant market by blocking and delaying the entry or re-entry of competitors into the market." (*Id.*, ¶16.) Notably, the NJ court denied Par's motion to dismiss the complaint, stating, *inter alia*, that "[Fresenius'] allegation that [Par] engaged in an 'extensive anticompetitive scheme' by entering into exclusive arrangements to restrict entry of competitors, if proven, ***would constitute intentional illegal behavior***." (Ex. 4 at 10.)

Given these allegations of illegality regarding Par's dealings with vasopressin API suppliers, Eagle—as a prospective seller of generic vasopressin reliant on API supply—is understandably concerned about disclosure of the identity of Eagle's API supplier to Par. This legitimate concern is compounded by Par's refusal to confirm that its proposed designated in-house counsel were not involved in the alleged antitrust violations at issue in the *Fresenius* litigation, including the drafting, negotiation and approval of the allegedly unlawful API supplier agreements. Indeed, when Eagle requested such confirmation, Par's counsel would represent only that "***Fresenius*** has never identified Mr. Maletta or Mr. Brown ***in any interrogatory response or other disclosures*** as being involved in any alleged wrongdoing." (Ex. 5.) But whether ***Fresenius*** is aware of any involvement they might have had, or disclosed such awareness during discovery in the *Fresenius* action, is beside the point—that knowledge is uniquely in Par's possession. Par's refusal to unequivocally confirm their lack of involvement speaks volumes and forms the basis of Eagle's objection to their in-house designees.

Nor has Par identified any legitimate need for Par's in-house counsel to learn the identity of Eagle's API supplier. When pressed on this issue, Par's only response was to vaguely assert that it "could prove to be useful" in "identifying additional discovery and fact investigation to be pursued," and Par might at some point in the future consider bringing an unstated claim against the API supplier. (Ex. 6.) But Par failed to identify any such additional discovery, fact investigation or potential future claim (the basis for which is not apparent, given the patents-in-suit claim vasopressin ***formulations***, not API), nor explain why it would require in-house counsel involvement.

Under these circumstances, good cause exists to restrict the identity of the supplier to Par's outside counsel as the information is highly confidential, carries a high risk of misuse, and Par has not identified any legitimate need for its in-house counsel to have access to it. *See In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373, 1378 (Fed. Cir. 2010). Indeed, the identity of Eagle's API supplier is highly sensitive because vasopressin API suppliers are indispensable to making and selling any competing product, as reflected in Fresenius' allegations. Eagle respectfully requests that the "identity of the supplier of the active ingredient of a party's vasopressin product" be designated "Highly Confidential Information," and thus produced only to outside counsel. (*See* Ex. 1, ¶2(c)(i).) Furthermore, unless and until Par confirms that Mr. Maletta or Mr. Brown were not involved in any of the alleged wrongful acts at issue in the *Fresenius* litigation, Eagle's objection to their designation under the Protective Order to access Eagle's confidential information should be sustained. *Cf United States v. Dentsply Int'l, Inc.*, 187 F.R.D. 152, 159–62 (D. Del. 1999) (denying access by antitrust defendant's counsel to competitors' information because "he could make use of this information to augment Dentsply's efforts in making or implementing strategic acquisitions" and contractual role "entails an unacceptably high risk of either utilization or inadvertent disclosure of confidential information").

II. Dispute 3: "FDA Bar" Scope

The parties' third dispute, regarding the scope of the "FDA Bar" in ¶2(k)(ii) of the proposed Protective Order, is narrow. The parties have agreed in principle to precluding designated in-house counsel from "the preparation or submission of any FDA documents . . . regarding approval requirements relating to vasopressin." The parties dispute only whether an exception should be provided for in-house counsel to work on ***their own employer's*** FDA applications.

Par's proposal to preclude designated in-house counsel from working on ***any*** FDA submission is contrary to precedent requiring a balance between "the risk of inadvertent disclosure or improper use of confidential information . . . [and] the potential harm of restricting a party's right to continued representation by its counsel." *See Edwards Lifescis. AG v. CoreValve, Inc.*, 699 F.3d 1305, 1316 (Fed. Cir. 2012). Not every FDA activity presents the same level of risk. Indeed, the general purpose of an FDA bar like the one proposed is to prevent a party from using the other party's confidential information to interfere with their regulatory approvals, for example, through the filing of a "citizen's petition" with the FDA. *Cf. In re Brimonidine Patent Litig.*, No. 07-md-1866-GMS, 2008 WL 4809037, at *4 (D. Del. Nov. 3, 2008) (denying leave to use confidential information in citizen's petition). Involvement with such petitions poses a high degree of risk.

By contrast, regulatory activities regarding a party's own FDA application pose little risk because the other party's confidential information is of little to no use. Nor has Par identified any such risk. Rather, its only purported basis for rejecting Eagle's proposal is that it is "one-sided" because Par's product has been approved while Eagle's is pending. Absent any prejudice to Par, however, any alleged one-sidedness is not a basis to apply unnecessary restrictions. That is particularly the case given the disparity in resources. Eagle has just one in-house counsel handling IP matters, Ms. Pearl Siew, who has been and will be involved with Eagle's application as well as this litigation. Because Ms. Siew is Eagle's only potential in-house counsel designee, adopting Par's blanket proposal would prevent Eagle from designating ***any*** in-house counsel. *See, e.g.*, *Vivus, Inc. v. Actavis Labs FL, Inc.*, Civ. A. No. 14-cv-3786 (SRC)(CLW), 2016 WL 590212, at *5 (D.N.J. Feb. 11, 2016) ("Vivus has 'only two in-house attorneys . . .' . Actavis' bars would work considerable prejudice on Vivus by significantly curbing both the duties Dr. Wells would be able to perform as well as Vivus' ability to choose its counsel and pursue its business and litigation strategies."). Par, though, has already identified two in-house counsel who (subject to Eagle's above objection) can be designated yet not need to be involved in regulatory activities, and presumably it has more as well.

Moreover, Par's "one-sidedness" argument is incorrect because the proposed exception would apply to each party's in-house counsel equally, allowing Par's counsel to work, for example, on submissions relating to any new vasopressin product or formulation, and any regulatory issues regarding its currently approved formulation. In short, Par's blanket proposal is unnecessary and would only serve to prejudice Eagle's ability to have equal support of in-house counsel.

III. Conclusion

For the foregoing reasons, Eagle respectfully requests that the Court adopt its proposed Protective Order provisions (Ex. 1), and sustain Eagle's objection to the designation of Mr. Brown and Mr. Maletta as in-house counsel qualified under the Protective Order pending confirmation they were not involved in the allegedly improper conduct at issue in the *Fresenius* action.

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

BAP/msb/6046073/45185

cc: Clerk of the Court (via hand delivery)
Counsel of Record (via electronic mail)